

REMARKS

Applicants have received and carefully reviewed the final Office Action mailed June 21, 2011. Reconsideration and withdrawal of the rejections are respectfully requested.

Allowed Claims

Applicants thank the Examiner for indicating that claims 27, 30-36, 38-41, 47, and 48 are allowed.

Rejection under 35 U.S.C. § 103(a)

Claims 18-23, 25, 26, and 46 are rejected as being unpatentable over Foley (US 5,792,044) in view of Ash (WO 83/03189) and Zdeblick (US 6,206,922). Applicants respectfully traverse the rejection. Independent claim 18 recites:

- 18. (previously presented) A system for performing a fixation procedure at a spinal location within a patient, comprising:
 - at least two fasteners adapted to be fixed to two adjacent vertebrae;
 - an elongate body having a proximal end and a distal end and defining a length between the proximal and distal ends such that the proximal end can be positioned outside the patient and the distal end can be positioned inside the patient adjacent the spinal location, the elongate body having an outer surface and an inner surface, the inner surface defining a passage extending between the proximal and distal ends sized to permit passage of the at least two fasteners therethrough; and
 - a fixation element sized to pass through the passage of the elongate body and configured to engage the at least two fasteners;
 - wherein the elongate body is actuatable between a first configuration sized for insertion into the patient and a second configuration wherein the cross-sectional area of said passage at a first location is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location; wherein the cross-sectional area of said passage at said first location is sized to permit visualization of two fasteners fixed to two adjacent vertebrae; wherein the elongate body is configured such that the passage provides unobstructed access from the proximal end to the distal end when in the second configuration.

None of Foley, Ash, Zdeblick, or a combination thereof appears to teach or suggest such a structure. The Examiner acknowledges that Foley fails to disclose a system comprising an elongate body that is actuatable as claimed. Zdeblick also does not appear to teach an elongate body that is actuatable as recited in the claim. Ash is cited as teaching a device having an

elongated body expandable at the distal end to provide viewing and operation room. The Examiner asserts that it would have been obvious to manufacture the device of Foley with an expandable distal end in view of Ash to provide viewing and operation room. The Examiner has not indicated, in the rejection itself, any reference that teaches or suggests a device as claimed in which the passage provides unobstructed access from the proximal end to the distal end when in the second configuration. The Examiner has also not indicated why one of ordinary skill in the art would have been motivated to modify Foley, Ash, and Zdeblick to achieve the claimed structure. Applicants submit that even if one were to combine Foley, Ash, and Zdeblick, one would not arrive at the system as claimed.

In the Response to Arguments section, the Examiner asserts that Foley clearly discloses a device having an unobstructed passage, thus Ash does not need to teach the passage being unobstructed since this limitation is already disclosed in Foley. Applicants respectfully disagree that this is the end of the analysis. Applicants acknowledge that Foley teaches a device with an unobstructed passage, however, the passage is not actuatable. Ash appears to be the only reference that teaches an actuatable device, thus the mechanism providing the actuation must be considered in any combination. The rejection appears to be made on the basis of combining the actuation feature of Ash with the fixation systems of Foley and Zdeblick, thus it appears the combined teachings must be addressed. Because Ash contains the only teaching of an actuated device, the actuation mechanism is the only means available for making the asserted combined device. The Examiner has not provided any other means of actuation. As can be seen in FIG. 2 of Ash, the actuation mechanism 32 is located within the tube 12, with the actuator 32 urging the levers 28 apart when the internal conduit 34 is moved relative to the external tube 12. The internal conduit 34 of Ash appears to provide an unobstructed passage but this conduit is not itself actuatable, as seen in FIGS. 1-2. The part of Ash that is actuatable is the levers 28 at the distal end of the external tube 12. However, the outer tube 12 cannot be seen to be a passage that provides unobstructed access from the proximal end to the distal end when in the second (expanded) configuration. As is clearly seen in FIG. 2, the actuator 32, internal conduit 34, and access channel 88 at least partially obstruct the passage defined by the inner surface of the outer tube 12. Thus, there does not appear to be any structure in Ash that can be considered to form a passage with an unobstructed access from the proximal end to the distal end when in the second (expanded) configuration. The fact that Foley teaches a fixed cannula with an unobstructed

passage does not provide a solution. If one were to combine the unobstructed passage cannula of Foley with the actuatable device of Ash, the internal actuation mechanism of Ash must be considered because no other actuation mechanism is taught or suggested by the combination of references, and the Examiner has not provided any rational reasoning for modifying the internal actuation mechanism of Ash. The Examiner asserts that Applicants cannot argue on a piece-meal basis. While Applicants' arguments may appear to be piece-meal, Applicants are merely pointing out that none of the cited references appear to teach a claimed element, and the Examiner has not provided any additional reasoning for achieving the claimed element. Applicants have considered all of the teachings of Foley, Ash, and Zdeblick. However, as discussed above, Ash appears to provide the only actuation mechanism, which is clearly taught to be inside the outer tube. Because the only actuation mechanism is taught as being inside the tube, a combination of Ash, Foley, and Zdeblick would appear to have an internal actuation mechanism.

The Examiner appears to be asserting that because Ash teaches a device that can be actuated, and Foley teaches an unobstructed fixed cannula, that somehow, one could make the unobstructed cannula of Foley be actuated, but without using the internal actuation mechanism of Ash. The Examiner has not provided any teaching or suggestion of an alternative actuation mechanism that would actuate the cannula of Foley while allowing the cannula to remain unobstructed. Further, Applicants note that the claimed passage is defined by the inner surface of the elongate body, and it is the cross-sectional area of the passage in the second configuration that is greater at a first location distal to a second location. If one considers the tube 12 of Ash to be the elongate body, then the inner surface defines the passage, which, as clearly seen in FIG. 2, is obstructed by the actuator 32, the internal conduit 34, and the access channel 88. The Examiner asserts that these elements "are not part of the passage, but are placed within the passage which gives these structures and elements unobstructed access from the proximal end of the elongate member to the distal end of the elongate member in the second configuration as shown clearly in Figure 2." Applicants respectfully disagree. Ash teaches the actuator means 32 and internal conduit 34 as being part of the device and connected to the tube 12, in order to provide the actuation of the levers 28. Ash specifically teaches:

As shown in the embodiment of FIGURES 1-3 the actuator means 32 includes a mechanical linkage 46 mechanically interconnecting the internal conduit 34 and

the levers 28. As the internal conduit 34 is moved proximally with respect to the external tube 12, the mechanical linkage 46 extends outwardly to urge the distal ends 44 levers 28 apart.

See page 7, lines 8-14 and FIGS. 1-3. Ash clearly teaches the actuator means 32 and internal conduit 34 as part of the device, disposed within the tube 12 as seen in the figures. One of ordinary skill in the art would understand from the teachings of Ash that the actuator means 32 and internal conduit 34 is not inserted into the tube 12 but is instead part of the tube structure. The Examiner asserts that "[i]f the device of Ash did not have an unobstructed passage from the proximal end to the distal end of the elongate member, then those structures and elements would not be able to perform any functions on the patient." Applicants acknowledge that Ash appears to provide an unobstructed passage in the form of the internal conduit 34, but conduit 34 is not actuatable. Ash appears to teach an obstructed passage defined by the inner surface of actuatable tube 12, and an unobstructed but non-actuatable passage defined by the internal conduit 34. Ash thus cannot be seen to teach the claimed elements.

Regardless of which parts of Ash are considered the elongate body, the structure of Ash cannot be seen to provide an unobstructed passage as claimed. While the rejection is based on the combination of Foley, Ash, and Zdeblick, none of the references appears to provide a teaching or suggestion of the claimed structure. Further, the Examiner has not provided a rational reason for one of ordinary skill in the art to modify the combined references to achieve the structure as claimed.

If the rejection is maintained, Applicants respectfully request the Examiner indicate how the combination of the fixed cannulas of Foley and Zdeblick, when combined with the internally actuated device of Ash, would achieve the claimed structure. Alternatively, the Examiner is respectfully requested to provide a rational reason why, upon reviewing Foley, Ash, and Zdeblick, one of ordinary skill in the art would have been motivated to combine the references and then further modify the combination to change the actuation mechanism to achieve the claimed structure. Reconsideration and withdrawal of the rejection are respectfully requested.


Conclusion

Reconsideration and reexamination are respectfully requested. It is submitted that, in light of the above remarks, all pending claims are now in condition for allowance. If a telephone interview would be of assistance, please contact the undersigned attorney.

Respectfully submitted,
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By his Attorney,

Date: 8/16/11



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